Consolidated Health Informatics

Standards Adoption Recommendation

Interventions & Procedures
PART B: Laboratory Test Order Names

Index

Summary

Domain: Interventions & Procedures
Laboratory Test Order Names

Standards Adoption Recommendation:
Logical Observation Identifier Names and Codes (LOINC®)

SCOPE
The representation of the names of laboratory test associated with an order within a computer system. Laboratory Results Naming, laboratory test result values, demographics, anatomy and physiology, and genes and proteins are not included in this domain and are the subjects of separate reports. The team recognizes that many of these vocabularies will also be incorporated in a comprehensive laboratory order system.

RECOMMENDATION
The work group recommends that LOINC® be adopted with identified gaps to be addressed to improve utility.

OWNERSHIP
The Regenstrief Institute, Inc. owns LOINC®.

APPROVALS AND ACCREDITATIONS
LOINC® has been approved by full standard development organization vote by HL7® v2.4 as a coding system for observation identifiers.

ACQUISITION AND COST
The LOINC® database and associated documents and programs are copyrighted, but the copyright permits all commercial and non-commercial uses in perpetuity at no cost. The LOINC® database can be obtained from the Regenstrief LOINC® website (http://www.regenstrief.org/LOINC). The website makes available a User's Guide, the free RELMA® (Regenstrief Logical Mapping Assistant) program, and the RELMA® User's Manual. RELMA® is a program for browsing the LOINC® database for mapping local test codes to LOINC® codes.

Part I – Team & Domain Scope Identification

Target Vocabulary Domain

Common name used to describe the clinical/medical domain or messaging standard requirement that has been examined.

Laboratory Test Order Names

Describe the specific purpose/primary use of this standard in the federal health care sector (100 words or less)

Laboratory test names used in ordering a test.

Sub-domains *Identify/dissect the domain into sub-domains, if any. For each, indicate if standards recommendations are or are not included in the scope of this recommendation.*

Domain/Sub-domain	In-Scope (Y/N)
Laboratory test name for clinical pathology orders	Y
Laboratory test panel names for clinical pathology orders	Y
Laboratory test name for anatomical pathology orders	Y
Laboratory test panel names for clinical pathology orders	Y
Genes and Proteins	N*****
Anatomy and Physiology	N*****

N* indicates that this domain is outside the scope of this group and will be the subject of a report by another work group. However, ordering systems will ultimately incorporate these vocabularies.

Information Exchange Requirements (IERs) *Using the table at appendix A, list the IERs involved when using this vocabulary.*

See "Part A" of Interventions and Procedures (Non-laboratory) report.

Team Members *Team members' names and agency.*

Name	Agency/Department
Jim Sorace (Team Lead)	**HHS/CMS**
Jorge Ferrer	HHS/CMS
Judith Johnson	VA
Mike Lincoln	VA
Catherine Moore	HHS/IHS

Nancy Orvis	DoD
Donna Pickett	HHS/CDC/NCHS
Allen Remaley	HHS/NIH
Steve Rosenfeld	HHS/NIH
Martin Tenney	Dod

Work Period *Dates work began/ended.*

Start	End
June 2003	August 2003

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

LOINC®

Ownership Structure *Describe who "owns" the standard, how it is managed and controlled.*

The Regenstrief Institute LOINC® Committee divides the LOINC® development into several divisions; the first of these is laboratory LOINC®. The clinical LOINC® division is concerned with non-laboratory diagnostic studies, critical care, and nursing measures, as well as the history, physical, and survey instruments. The clinical LOINC® division includes a number of new projects for defining clinical notes, report titles, and dental observations.

Summary Basis for Recommendation *Summarize the team's basis for making the recommendation (300 words or less).*

LOINC® has received prior recommendation as the CHI standard for Laboratory Test Result Names. Our recommendation recognizes that LOINC® is flexible enough to meet the needs of the Laboratory Test Order domain as well. This recognizes that LOINC® is the most complete, flexible, available, and widely accepted terminology of laboratory tests names. LOINC® also has codes for public health and veterinary test. These form a useful nucleus for environmental and homeland defense based test names, but will need continued development (LOINC® is continuing to expand this area). As in the prior CHI report the Laboratory Test Order work group recommends that LOINC® improve its structure by addressing issues such as test panel names, and adoption of hierarchical features to make it more comprehensive and flexible. These and other gaps are addressed below. Further our work group recognizes that LOINC® has been accepted by HL7® as a standard, and that the CHI has accepted HL7® as the standard messaging format. Several recommendations regarding the use of LOINC® and integrating it with HL7® are also made in the "Gaps" section below. Finally, LOINC® does not contain all the vocabularies that may need to be incorporated into a HL7® based laboratory order representation. Rather than make a blanket recommendation (e.g. SNOMED CT® or UMLS® 0), the group felt that other groups would accomplish much of this work. For example anatomy and physiology, genes and proteins, drugs and devices, and patient demographics work groups will all contain vocabulary elements that may be required to complete an order.

Conditional Recommendation *If this is a conditional recommendation, describe conditions upon which the recommendation is predicated.*

Please note that recommendations 1 to 5 are LOINC® specific while numbers 6 and 7 are suggestions for further collaboration between the LOINC® and HL7® communities. The work group stresses that the recommendation to use LOINC® is conditional on successfully addressing items 1 and 2 in this section. ***(Update April 04: Recommendation's conditions regarding hierarchies and panels have been addressed by LOINC® and ongoing work continues. CHI will continue to monitor and collaborate with LOINC®)***

1. Introduction of a hierarchy to LOINC® would allow for standard aggregation of terms across the healthcare system, ease in identifying needed terms, and identification of terms to assign within an institution. Further this would assist development of useful Laboratory Test Ordering Applications by allowing healthcare providers to search under a common name (e.g. Chem 6) with the application performing the mapping to the laboratories underlying LOINC® codes in a consistent manner. A similar example is outlined in the LABORATORY TEST RESULTS NAMES report. The hierarchy should support generic test codes that do not specify a specimen or method (allowing these to be mapped latter by the institutions laboratory to the exact specimen and method requirements in use at that time). I would also be desirable if the hierarchy noted the preferred order code for the test, thus helping to standardize order forms.
2. The naming of panels is problematic and needs further development. LOINC® is currently working actively on this problem. As most individual analyte tests are ordered as parts of panels, providing a workable solution for this issue is extremely important, and would significantly increase the speed of adoption by vendors. Further panel codes that allow the laboratory to specify the exact test to be run need to be developed. For example in the area of disease surveillance reference laboratories frequently change there test panels based on the most recent epidemiological findings, also the subsequent testing on the sample may depend on what organism is initially found.
3. The improvements noted in the LABORATORY TEST RESULTS NAMES report in content coverage, definitions, and unrecognized synonymy is noted and also very relevant for ordering.
4. LOINC® has been working to integrate genomic test by allowing users to search for relevant genetic test using a disease specific key word strategy. This will need to be expanded to include gene array and proteomic based laboratory tests. LOINC® is aware of these issues. LOINC® may also consider allowing users to search by gene name if appropriate.
5. Recognizing there are copyright issues, the availability of a map from LOINC® to CPT® codes would be helpful to produce administrative data (claims) from clinical applications.
6. HL7® Laboratory Order formats are very flexible and broad. LOINC® in

collaboration with HL7® might consider developing a series of more narrowly focused domain and use case message standards that are specific for the various sections found in both clinical pathology (chemistry, microbiology, hematology etc.) and anatomic pathology (surgical, cytology and autopsy). Each standard should include an audit trial that would include referrals to reference laboratories or changes to the order. The purpose of this trail would be to ensure that both the original message content and any subsequent changes could be reconstructed. As the current standard is very flexible, this work actually represents developing subsets of the current standard, and is a refinement of the work already in progress.

7. LOINC® in collaboration with HL7® might recommend the addition of global positioning system data and other relevant information from "field samples".

Approvals & Accreditations

Indicate the status of various accreditations and approvals:

Approvals & Accreditations	Yes/Approved	Applied	Not Approved
Full SDO Ballot	Yes, as part of HL7® v2.4 as a coding system for observation identifiers		
ANSI	HL7®		LOINC®

Options Considered *Inventory solution options considered and summarize the basis for not recommending the alternative (s). SNOMED must be specifically discussed.*

SNOMED® - The Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) is a product of the College of American Pathologists. It is designed to "capture information about a patient's history, illnesses, treatment and outcomes" (source: www.snomed.org). SNOMED® is not designed to name laboratory results, and in fact is cross-mapped to LOINC® for this purpose. SNOMED CT® has integrated "LOINC® MA". This version was released in August 1999 and contains 21,298 terms. Independently Snomed includes an additional 8,932 laboratory test concepts. The most current version of LOINC® is 2.09. It contains over 33,000 names including 2382 allergy, Blood bank 607, Cell markers 532, Challenge terms (chemistry) 1462, Chemistry 5063, Coagulation 373, Cytology 47, Drug/Toxicology 4253, Drug Dosage 365, Fertility testing 111, Hematology 1081, HLA 335, Microbiology/Serology 6696 Molecular

pathology 261, Pathology 138, serology 851, skin test 31, UA 195, Panels 65. Regenstrief also has an application named RELMA® that allows users to enter a list of their local test names and map them to LOINC® codes see (http://www.LOINC.org/). Regenstrief also plans to collaborate directly with NLM in mapping LOINC® into UMLS®/MESH Perhaps more problematically; the LOINC® mapping is not covered by the agreement between UMLS® and CAP, and would require a separate license. Finally, the hierarchies developed to support LOINC® will be optimized for the laboratory environment, and these relationships may not be retained when mapped into Snomed or UMLS®. Thus it is desirable to select LOINC® as a root standard and avoid integration with other vocabularies that might lead to a "forked standard".

CPT® – CPT® coding was also considered. However the group felt that it lacked the granularity necessary for a useful laboratory ordering vocabulary. Also, outside of billing, CPT® lacks penetration. For example it is not used by laboratories for result reporting, and was not recommended as a standard in this area. The work group concluded that it would be best to map CPT® codes to LOINC®. This would allow one common laboratory standard to be developed for ordering, results and possibly billing.

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today?
What number of or percentage of relevant vendors have adopted the standard?
What number or percentage of healthcare institutions have adopted the standard?
What number or percentage of federal agencies have adopted the standard?
Is the standard used in other countries?
Are there other relevant indicators of market acceptance?

The LOINC® codes were initially released on the Internet in April of 1995. Since then, seventeen revisions of the LOINC® database have been released and it now includes over 30,000 observation concepts. The informatics committee of the College of American Pathologists has endorsed the LOINC® codes. The American Clinical Laboratory Association (ACLA), an association of large referral laboratories whose members are responsible for more than 60% of US outpatient laboratory test volume, has recommended LOINC® for adoption by its members. Quest Diagnostics (formerly Corning MetPath), LabCorp, and SmithKline Beecham (now part of Quest Diagnostics), three of the largest commercial laboratories in the US, have adopted LOINC® as their code system for reportable test results, as has ARUP (Associated Regional and University Pathologists). Mayo Medical Laboratories is currently mapping their tests to LOINC®. In addition, the University of Colorado, Intermountain Health Care, Promedica, Kaiser Permanante, Clarian Health (Indiana University, Methodist Hospital, and Riley Hospital), Partners Healthcare System of Boston (Brigham and Women's and Mass

General Hospital), Care Group of Boston, Mayo Medical Group, the Hospital for Sick Children in Toronto, New York-Presbyterian Hospital, the University Hospitals of Columbia and Cornell, the Department of Veterans Affairs, and the Department of Defense are adopting the LOINC® codes for laboratory reporting. All US veterinary medicine laboratories have committed to the use of LOINC®. HMOs such as Empire Blue Cross and Aetna Health Care are also adopting LOINC® for internal purposes. Internationally, LOINC® has also met success. The Swiss Center for Quality Control (Geneva, Switzerland) is adopting LOINC® for quality assurance mandates. The provinces of Ontario and British Columbia, Canada, are adopting LOINC® codes province wide, and Newfoundland is considering following in their footsteps. Most recently, Germany has adopted LOINC® for national use. LOINC® is used in Australia, Korea, Estonia, Brazil, and New Zealand. The LOINC® codes have been incorporated into the National Library of Medicine's UMLS®. They have been incorporated in CMS's quality assurance testing pilot programs. They have been adopted by the Centers for Disease Control and Prevention/Council of State and Territorial Epidemiologists' project for electronically reporting/transmitting communicable disease information and by NAACCR (North American Association of Central Cancer Registries) for their tumor registry variables. LOINC® and SNOMED® are also supporting a collaboration that will ensure a consistent, unambiguous clinical reference terminology that builds upon the strengths of each.

Among laboratory information systems (LIS), a survey published by the College of American Pathologists in November 2000 revealed that LOINC® code indexes were provided in 33 LIS systems, representing 10,914 installed LIS sites. The Department of Defense Composite Health Care System also incorporated a LOINC® index code during 2001. The current version of CHCS containing the LOINC® index is now deployed to all 103 DoD laboratories. The Veterans' Affairs system, VISTA, has also incorporated a LOINC® Index and is collaborating with DoD on an interoperability project that will utilize LOINC® codes for results transfer between DoD, VA, and commercial reference laboratories.

Part III – Adoption & Deployment Information

Provide all information gathered in the course of making the recommendation that may assist with adoption of the standard in the federal health care sector. This information will support the work of an implementation team.

Existing Need & Use Environment

Measure the need for this standard and the extent of existing exchange among federal users. Provide information regarding federal departments and agencies use or non-use of this health information in paper or electronic form, summarize their primary reason for using the information, and indicate if they exchange the information internally or externally with other federal or non-federal entities.

Column A: Agency or Department Identity (name)
Column B: Use data in this domain today? (Y or N)
Column C: Is use of data a core mission requirement? (Y or N)
Column D: Exchange with others in federal sector now? (Y or N)
Column E: Currently exchange paper or electronic (P, E, B (both), N/Ap)
Column F: Name of paper/electronic vocabulary, if any (name)
Column G: Basis/purposes for data use (research, patient care, benefits)

Department/Agency	B	C	D	E	F	G	Comments
Department of Veterans Affairs	Y	Y	Y	B	LOINC®, local terms, and free text	Research, Patient care & Benefits	
Department of Defense							
HHS Office of the Secretary							
Administration for Children and Families (ACF)							
Administration on Aging (AOA)							
Agency for Healthcare Research and Quality (AHRQ)							
Agency for Toxic Substances and Disease Registry (ATSDR)							

Centers for Disease Control and Prevention (CDC)							
Centers for Medicare and Medicaid Services (CMS)							
Food and Drug Administration (FDA)							
Health Resources and Services Administration (HRSA)							
Indian Health Service (IHS)							
National Institutes of Health (NIH)							
Substance Abuse and Mental Health Services Administration (SAMHSA)							
Social Security Administration							
Department of Agriculture							
State Department							
US Agency for International Development							
Justice Department							
Treasury Department							
Department of Education							
General Services Administration							
Environmental Protection Agency							
Department of Housing & Urban Development							
Department of Transportation							

Homeland Security							

As is Agency Specific Needs for LOINC®

Department of Veterans Affairs

The Veterans Health Administration (VHA) used its FY2001 $21 billion budget to serve over 4.2 million veterans, including three quarters of disabled and low-income veterans. VHA employs approximately 180,000 health care professionals at 163 hospitals, more than 800 community and facility-based clinics, 135 nursing homes, 43 domiciliaries, 206 readjustment counseling centers and various other facilities. VHA has an extensive computerized information system, VistA, to manage clinical information at each care delivery site.

The sharing of clinical data between sites, and the provision of comparable data across sites for research and management purposes is a high priority within VHA. Laboratory results and medications are felt to be highly valuable and achievable domains. In fact, the Under Secretary for Health mandated the use of LOINC® in each VistA system in 2001.

Department of Defense

The Department of Defense has incorporated LOINC® into the Composite Health Care System (CHCS), which is utilized by 103 DoD military treatment facilities world-wide. Within the CHCS standard laboratory test file, approximately 6,100 laboratory tests are mapped to LOINC® codes. DoD is currently sponsoring a Global Laboratory Information Transfer (GLIT) project to implement the transfer of laboratory orders and results between DoD military treatment facilities, VA treatment facilities, and commercial reference laboratories utilizing LOINC® codes as laboratory test result identifiers.

Department of Health and Human Services

HHS Agency	***Potential use of Laboratory LOINC®***
Office of the Secretary	Limited to no direct use. Planning requires knowledge of use and limitations.
Administration for Children and Families (ACF)	Limited to none.
Administration on Aging (AOA)	Limited to none.
Agency for Healthcare Research and Quality (AHRQ)	Extensive as many of their programs involve in depth knowledge of medical laboratory results. Agency is actively involved in CHI and external standard setting and is already knowledgeable on laboratory LOINC®.
Agency for Toxic	Many of their programs involve in depth knowledge of medical and

Substances and Disease Registry (ATSDR)	other laboratory results. Agency follows CDC policy (below) on laboratory LOINC® and is knowledgeable.
Centers for Disease Control and Prevention (CDC)	Extensive as many of their programs involve in depth knowledge of laboratory results. Agency already endorses the use of laboratory LOINC® for use in the National Electronic Surveillance System (NEDSS), and is actively involved in both CHI and external standard setting.
Centers for Medicare and Medicaid Services (CMS)	Limited at present, but may expand as laboratory LOINC® is more widely used in quality improvement programs. Agency is actively involved in CHI and external standard setting.
Food and Drug Administration (FDA)	Limited at present, but will expand as laboratory LOINC® is more widely used in patient medical record systems and hence clinical trails. Agency is actively involved in external standard setting but currently has limited CHI involvement.
Health Resources and Services Administration (HRSA)	Limited at present, but will expand as laboratory LOINC® is more widely used in the care-providing portions of their programs. Agency is involved in external standard setting but currently has limited CHI involvement.
Indian Health Service (IHS)	Extensive as their treatment facilities will be using laboratory LOINC® for coding of test results in record system. Agency is actively involved external standard setting and works closely with both the Department of Veterans Affairs and Department of Defense in the development and deployment of clinical record systems.
National Institutes of Health (NIH)	Extensive as many of their programs involve in depth knowledge of laboratory results. Portions of the Agency are already extensively involved in CHI and external standard setting.
Substance Abuse and Mental Health Services Administration (SAMHSA)	Limited at present, but will expand as laboratory LOINC® is more widely used in substance testing laboratories and the care-providing portions of their programs. Agency is involved has limited CHI and external standard setting involvement.

Number of Terms

Quantify the number of vocabulary terms, range of terms or other order of magnitude.

LOINC®:

The most current version of LOINC® is 2.09. It contains over 33,000 names including 2382 allergy, Blood bank 607, Cell markers 532, Challenge terms (chemistry) 1462, Chemistry 5063, Coagulation 373, Cytology 47, Drug/Toxicology 4253, Drug Dosage 365, Fertility testing 111, Hematology 1081, HLA 335, Microbiology/Serology 6696 Molecular pathology 261, Pathology 138, serology 851, skin test 31, UA 195, Panels 65. Regenstrif also has an application named RELMA® that allows users to enter a list of their local test names and map them to LOINC® codes see (http://www.LOINC®.org/).

Regenstrif also plans to collaborate directly with NLM in mapping LOINC® into UMLS®/MESH.

HL7®:
Not Applicable – messaging standards

How often are terms updated?New releases of the LOINC® database and/or RELMA® program occur 3-4 times per year

Range of Coverage

Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)

Lab LOINC® is implementable now. It is not complete and never will be. No clinical terminology is static. Maintenance to grow and evolve LOINC® is ongoing.

HL7® Standards are available from HL7®. HL7® asserts and retains copyright in all works contributed by members and non-members relating to all versions of the Health Level Seven® standards and related materials unless other arrangements are specifically agreed upon in writing. No use restrictions are applied.

Acquisition: ***How are the data sets/codes acquired and use licensed?***
The LOINC® database can be obtained from the Regenstrief LOINC® website (http://www.regenstrief.org/LOINC®/),

The LOINC® database and associated documents and programs are copyrighted, but the copyright permits all commercial and non-commercial uses in perpetuity at no cost. If the LOINC® database or its contents are distributed as a database, such distributions must include all of the parts of the formal LOINC® term, the LOINC® short name, the LOINC® code, the deprecated flag, and the copyright. No such notice is required when LOINC® codes are used in messages to report test results.

Cost: ***What is the direct cost to obtain permission to use the data sets/codes? (licensure, acquisition, other external data sets required, training and education, updates and maintenance, etc.)***

LOINC®:

The LOINC® database and associated documents and programs are copyrighted, but the copyright permits all commercial and non-commercial uses in perpetuity at no cost.

Costs related to training & education, integration into existing systems and other implementation related issues can only be estimated in context of the specific implementation project and estimates will not be provided as part of this document

Systems Requirements

Is the standard associated with or limited to a specific hardware or software technology or other protocol?

Systems must be able to integrate the LOINC® distribution, which is available as a PDF report sorted alphabetically by class, as a tab delimited ASCII text file, and/or as an Access database.

Guidance

What public domain and implementation and user guides, implementation tools or other assistance is available and are they approved by the SDO?

LOINC®:

http://www.regenstrief.org/LOINC®/ provides the 72-page LOINC® Users' Guide (PDF), the free RELMA® program, which downloads with full LOINC® access to the database, and the RELMA® Users' Manual. RELMA® is a program for browsing the LOINC® database and for mapping local test codes to LOINC® codes.

Is a conformance standard specified? Are conformance tools available?

Maintenance

How do you coordinate inclusion and maintenance with the standards developer/owners?
What is the process for adding new capabilities or fixes?
What is the average time between versions?
What methods or tools are used to expedite the standards development cycle?
How are local extensions, beyond the scope of the standard, supported if at all?

LOINC® has 4-6 committee meetings per year, half clinical and half laboratory. At least one laboratory and one clinical meeting are open to the public. New releases of the LOINC® database and/or RELMA® program occur 3-4 times per year. The LOINC® committee welcomes suggestions about observation terms that have not yet been included in the LOINC® database. The LOINC® Users' Guide defines the structure and format required for new submissions.

Customization

Describe known implementations that have been achieved without user customization, if any.

See implementation section above

If user customization is needed or desirable, how is this achieved? (e.g, optional fields, interface engines, etc.)

Mapping Requirements

Describe the extent to which user agencies will likely need to perform mapping from internal codes to this standard.

Extensive, unless systems are already mapped.

Identify the tools available to user agencies to automate or otherwise simplify mapping from existing codes to this standard.

http://www.regenstrief.org/LOINC®/ provides the 72-page LOINC® Users' Guide (PDF), the free RELMA® program, which downloads with full LOINC® access to the database, and the RELMA® Users' Manual. RELMA® is a program for browsing the LOINC® database and for mapping local test codes to LOINC® codes. We anticipate that the SDO will collaborate with other vocabulary efforts such as SNOMED CT®, and that these vocabularies will be mapped through programs such as the UMLS® Metathesaurus.

Compatibility

Identify the extent of off-the-shelf conformity with other standards and requirements:

LOINC®

Conformity with other Standards	Yes (100%)	No (0%)	Yes with exception
NEDSS requirements	**x**		
HIPAA standards	**x**		
HL7 2.x	**x**		

Implementation Timeframe

Estimate the number of months required to deploy this standard; identify unique considerations that will impact deployment schedules.

Conversion to Lab LOINC®:
A recent presentation by Lee Min Lau (Lau, L M, Johnson, K, Monson, K, Lam, S H, Huff, S M. A method for the automated mapping of laboratory results to LOINC®. Proceeding of the AMIA Symposium 2000; 472-6: http://www.amia.org/pubs/symposia/D200807.PDF describes the numerous problems in translating the internal names for laboratory procedures into appropriate LOINC® codes. Conversations with this group indicate that the conversion of a laboratory doing a limited and standard test menu is generally quick; no more than a few weeks. In a laboratory doing many complex procedures, this process is prolonged. Conversion of the simple tests is generally short, again a few weeks. Assigning LOINC® codes to the remaining tests can take up to three months as the appropriate LOINC® code is identified through evaluation of actual usage of the test in the laboratory. (While the laboratory workers can detail what is stated in the procedure manuals, usage, particularly with regard to specimen type, may vary enough to change the LOINC® code.) The Regenstrief group found similar timeframes during their assignment of LOINC® codes to five Indianapolis hospitals.

Since these reports, the LOINC® Committee has expanded the ability of their RELMA® tool to identify the correct LOINC® code for a test from minimal input. They have also introduced more generic codes, particularly those not requiring specific identification of the method or specimen, to facilitate selection of an appropriate code. For those codes not identifying one of the axis components specifically, it is assumed that the missing element is identified elsewhere in the message. Continuing work on the RELMA® tool and the ability to automatically map a laboratory code list LOINC® is underway at the Regenstrief Institute.
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Gaps

Identify the gaps in data, vocabulary or interoperability.

Laboratory LOINC® Gaps:

LOINC® is a pre-coordinated non-structured list of terms a part of which is assigned to laboratory tests. The structure of LOINC® involves six axes: Component (Test Name), Property of Measurement (Concentration); Time Aspect (24 Hours); System (Specimen); Scale Type (Quantitative); and Method Type (Method Name). Each of the axes within a code is unique and unrelated to any other code. Codes that have similar components for one or more axes are also unrelated. Coordination and distribution of LOINC® is maintained under various grants from several government agencies to Regenstrief Institute, but the actual introduction of new codes to LOINC® involves voluntary submission of code sets from outsiders.

The following gaps need to be addressed before LOINC® can be recommended without qualification by the CHI Laboratory Name subgroup: ***(Update April 04: Gaps #1 & 2 have and are being addressed by LOINC®, recommendation is no longer "conditional")***

1. LOINC® needs to continue to improve coverage of test panels.

2. The Laboratory Test Order Name workgroup agrees with the Laboratory Test Results Name workgroup recommendation regarding the introduction of a hierarchy to LOINC® that would allow for standard aggregation of terms across the healthcare system, ease in identifying needed terms, and identification of terms to assign within an institution. The non-hierarchical nature of LOINC® makes consistent aggregation of concepts difficult. Preliminary work towards developing hierarchies is being considered by the LOINC® committee. The following example is relevant in both the test reporting and ordering activities.

For example, consider the test for Helicobacter Pylori, a commonly performed test done on peptic ulcer patients. LOINC® represents the possible tests for Helicobacter as:

LOINC®#	Component	Property	Time	System	Scale	Method
587-6	HELICOBACTER PYLORI	ACNC	PT	XXX	ORD	
22310-7	HELICOBACTER PYLORI AB	ACNC	PT	SER	ORD	IF
6419-6	HELICOBACTER PYLORI AB	ACNC	PT	SER	ORD	
7900-4	HELICOBACTER PYLORI AB	ACNC	PT	SER	QN	EIA
5174-8	HELICOBACTER PYLORI AB	ACNC	PT	SER	QN	IF
16929-2	HELICOBACTER PYLORI AB	ACNC	PT	SER	QN	
16533-2	HELICOBACTER PYLORI AB	TITR	PT	SER	QN	
5175-5	HELICOBACTER PYLORI AB	TITR	PT	SER	QN	LA
16125-7	HELICOBACTER PYLORI AB.	ACNC	PT	SER	ORD	
7901-2	HELICOBACTER PYLORIAB.I	ACNC	PT	SER	QN	
6420-4	HELICOBACTER PYLORI AB.	ACNC	PT	SER	QN	EIA
16126-5	HELICOBACTER PYLORI AB.	ACNC	PT	SER	ORD	
17859-0	HELICOBACTER PYLORI AB.	ACNC	PT	SER	ORD	EIA
7902-0	HELICOBACTER PYLORI AB.	ACNC	PT	SER	QN	
5176-3	HELICOBACTER PYLORI AB.	ACNC	PT	SER	QN	
16127-3	HELICOBACTER PYLORI AB.	ACNC	PT	SER		
7903-8	HELICOBACTER PYLORI AB.	ACNC	PT	SER	QN	
5177-1	HELICOBACTER PYLORI AB.	ACNC	PT	SER	QN	EIA
17780-8	HELICOBACTER PYLORI AG	ACNC	PT	STL	ORD	EIA

(note: ACNC = concentration, PT= point in time measure, SER = serum, ORD = ordinal scale, QN = quantitative scale, LA = latex agglutination, etc)

The 20 test elaborations here each represent a slightly different combination of component, property, time, system, scale, and method. All 20 are meaningfully distinct in the context of a laboratory system. However, there are really many fewer clinically meaningful combinations of tests. Usually the practitioner isn't concerned that the titre test is done by means of "LA" (latex agglutination) or by an alternative technique. For example, we might have the following aggregation at a clinical level:

LOINC®#	Component	Property	Time	System	Scale	Method
587-6 22310-7 6419-6 16126-5 17859-0	HELICOBACTER PYLORI AB (IgG or unspecified antibody reported as ordinal scale, e.g., 1+)	ACNC	PT	SER	ORD	various
7900-4 5174-8 16929-2 7902-0 5176-3	HELICOBACTER PYLORI AB (IgG or unspecified antibody reported as mass conc, e.g. 42 ng/ml)	ACNC	PT	SER	QN	various
16533-2 5175-5	HELICOBACTER PYLORI AB (IgG or unspecified antibody	TITR	PT	SER	QN	various

	reported as titre, e.g. 1:64 dilution)					
16125-7	HELICOBACTER PYLORI AB.IGA (IgA surface antibody by ordinal scale)	ACNC	PT	SER	ORD	
7901-2 6420-4	HELICOBACTER PYLORIAB.IGA (IgA surface antibody by mass conc)	ACNC	PT	SER	QN	
16127-3 7903-8 5177-1	HELICOBACTER PYLORI AB.IGM (IgM acute phase antibody indicating acute vs. old infection)	ACNC	PT	SER		
17780-8	HELICOBACTER PYLORI AG (Antigen—not antibody—stool test)	ACNC	PT	STL	ORD	EIA

But even this may be splitting hairs, as most reasonable clinicians could argue that there are only four "clinical tests":

LOINC®#	Component	Property	Time	System	Scale	Method
587-6 22310-7 6419-6 16126-5 17859-0 7900-4 5174-8 16929-2 7902-0 5176-5 16533-2 5175-5	HELICOBACTER PYLORI AB (IgG or unspecified antibody reported as ACNC ordinal scale or ACNC mass conc or Titre)	ACNC	PT	SER	QN or ORD	various
16125-7 7901-2 6420-4	HELICOBACTER PYLORIAB.IGA (IgA surface antibody by mass conc. or by ordinal scale)	ACNC	PT	SER	QN or ORD	various
16127-3 7903-8 5177-1	HELICOBACTER PYLORI AB.IGM (IgM acute phase antibody indicating acute vs. old infection)	ACNC	PT	SER	QN or ORD	various
17780-8	HELICOBACTER PYLORI AG (Antigen—not antibody—stool test)	ACNC	PT	STL	ORD	EIA

Most clinicians will wish to aggregate at the level of three types of antibody test results and positive antigen tests as shown directly above. A GI section division chief or pathologist at a particular site may wish to aggregate at even a higher level, such as how many resources are being expended on helicobacter pylori testing of all types (collapsing 20 tests into one category), but later that same day may be interested in something as finally grained as a single, atomic test when performing a research study that requires precise definitions.

7901-2	HELICOBACTER PYLORIAB.I	ACNC	PT	SER	QN	

3. Improvements are needed in content coverage, definitions, and unrecognized synonymy. The voluntary nature of term submission has lead to inadvertent duplication of terms, a density of term definitions in areas of interest to submitting topic experts, a sparseness of terms in areas where topic experts did not volunteer, and a lack of consensus in term definitions, especially with regard to the method axis and the combination of method and system axes.

Regenstrief Institute recognizes some of the above and is introducing more generic terms and establishing a hierarchy. They have introduced and are continually refining a software tool called the "Regenstrief LOINC® Mapping Assistant" (RELMA®) that imposes structure to LOINC® and makes term identification easier. A process to impose rigidity on code submission however appears lacking.

Obstacles

What obstacles, if any, have slowed penetration of this standard? (Technical, financial, and/or cultural)

LOINC® is widely distributed and has a high market penetration but the extent of use is not known.